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March 10, 2021

Via ECF To:

Special Master the Honorable Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th Floor
Philadelphia, PA 19103

**RE: *In re Valsartan Products Liability Litigation*, U.S. District Court
District of New Jersey, Camden Division, No. 1:19-md-02875**

Dear Special Master Vanaskie:

The following letter brief is submitted as a supplement regarding privilege designations pertaining to Meridan Consulting, and ToxRox Consulting, LLC. As previously outlined in the Defendants' Position Statement, filed on March 9, 2021, Aurobindo contends that it is premature to rule on these issues prior to the parties having had an opportunity to meet and confer after the disclosure of the "cast of characters" as required by SMO-5. However, without waiving that stance, and subject thereto, Aurobindo submits the following:

I. Background

On October 15, 2020, plaintiffs prepared a myriad of third party subpoenas. Among them were subpoenas addressed to Meridan Consulting, and ToxRox Consulting, LLC. Aurobindo objected to these subpoenas on the grounds the

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documents were protected by the attorney-client privilege and work product doctrine. The issue was briefed and oral argument was held before Judge Schneider on January 5, 2021, but to date, no ruling has been issued.

II. The Subpoenas Served on Meridian Consulting and ToxRox Consulting, LLC Should be Quashed Because They Encompass Documents Protected by the Work Product Doctrine And Attorney-Client Privilege

A. Work Product

The work product privilege offers qualified protection from disclosure of documents “prepared in anticipation of litigation rather than in the ordinary course of business.” *Tractenberg v. Township of West Orange*, 416 N.J. Super 354, 374, 4 A.3d 585, 597. A document is “prepared in anticipation of litigation if the ‘dominant purpose’ in preparing the document was concern about potential litigation and the anticipation of litigation was ‘objectively reasonable.’” *Id.*, (quoting *Miller v. J.B. Hunt Transp., Inc.*, 339 N.J. Super. 144, 150, 770 A.2d 1288 (App.Div.2001)). Notably, a document may “be found to have been prepared in anticipation of litigation even though litigation [has] not been commenced or even threatened when the document was prepared.” *Id.* “A document prepared at the direction of an attorney before litigation has commenced may be protected by the work product privilege if its use for litigation was the dominant purpose of preparing the document

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and if the attorney's belief that litigation would ensue was objectively reasonable.”

K.L. v. Evesham Tp. Bd. of Educ., 423 N.J. Super 337, 354, 32 A.3d 1136, 1145.

i. Consultants Engaged to Assist Outside Counsel in Providing Legal Advice On A Response to an FDA Warning Letter Possess Information Prepared In Anticipation of Litigation and, Thus, Protected by the Work Product Doctrine

The Subpoenas to Meridian and ToxRox should be quashed because all documents in their possession were prepared on behalf of Aurobindo in anticipation of litigation and, therefore, are protected by the Work Product Doctrine.

The work product doctrine encompasses “—“tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, **consultant**, surety, indemnitor, insurer, or agent).” Fed. R. Civ. P. 26(b)(3), *In re Niaspan Antitrust Litig.*, 2017 U.S. Dist. LEXIS 135753, *5-6, 2017 WL 3668907 (E.D.P.A. August 24, 2017). “[A] document satisfies Rule 26(b)(3) where in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation.” *Id.*, (quoting *Martin v. Bally's Park Place Hotel & Casino*, 983 F.2d 1252, 1258 (3d Cir. 1993)).

Aurobindo engaged both Meridian and ToxRox for assistance in providing legal advice to Aurobindo regarding its response to a regulatory agency’s

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notification of violations of federal regulations (i.e., an FDA Warning Letter).¹ The anticipation of litigation was objectively reasonable. In fact, this sort of relationship was examined, and the work product privilege was extended to a consulting firm hired by a pharmaceutical company's outside counsel to assist the company in responding to an FDA warning letter. *See Todd v. STARR Surgical Co.*, 2015 U.S. Dist. Lexis 189237 at *1, 2015 WL 13388227 (C.D. Ca. August 21, 2015) ("The work product privilege of Fed. R. Civ. P. 26(b)(3) applied to information provided by a consultant to assist a law firm in advising a client on how to respond to a federal agency warning letter because the consultant's work was performed in anticipation of future regulatory and legal proceedings, the consultant was hired to aid the firm in understanding the client's regulatory compliance and thereby assisted in the firm's provision of legal advice, and the routine aspects of the consultant's work in helping the client to improve its audit procedures could be viewed as preventing anticipated litigation and did not defeat the privilege"); *see also K.L. v. Evesham Tp. Bd. of Educ.*, 423 N.J. Super 337, 354, 32 A.3d 1136, 1145 ("A document prepared at the direction of an attorney before litigation has commenced may be protected by the work product privilege if its use for litigation was the dominant purpose of preparing the document and if the **attorney's belief that litigation would ensue was**

¹ Outside counsel for Aurobindo at the time was *not* the firm that represents them in this litigation, i.e., Cipriani & Werner, P.C.

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objectively reasonable”); *Miller v. J.B. Hunt Transp., Inc.*, 339 N.J. Super. 144, 150, 770 A.2d 1288 (App.Div.2001) (A document is “prepared in anticipation of litigation if the ‘dominant purpose’ in preparing the document was concern about potential litigation and the anticipation of litigation was ‘objectively reasonable.’”). Thus, any documents from Meridian and ToxRox are protected by the work product doctrine.

In re Niaspan Antitrust Litig. is also instructive here. The litigation involved a motion to compel discovery, *among which* included an email from a consultant, hired by one of the parties to create a compliance report with a co-promotion agreement.² *Id.* at *12. Based on the compliance report, if the entity was not in compliance, litigation would have ensued. *Id.* Based on this, the court ruled, “the report was therefore prepared in anticipation of litigation, and, **even though [the compliance report was] prepared by a consultant**, they were properly withheld as work product.” *Id.* In this case, much like *In re Niaspan Antitrust Litig.*, consultants were hired for the purpose of providing legal advice to the client on preparation of a document regarding regulatory compliance.

² Of note, prior to her ruling, the Honorable Jan DuBois examined, in camera, all the documents that were the subject of the Motion to Compel. *Id.* at *2.

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For the foregoing reasons, the subpoenas must be quashed, or, alternatively, a Protective Order must be entered prohibiting plaintiffs from obtaining the documents possessed by Meridan Consulting and ToxRox Consulting, LLC.

On January 5, 2021, Judge Schneider agreed that work performed by a consultant to assist in rendering legal advice could be protected by the work product doctrine if the primary purpose was preparation for litigation. See transcript of January 5, 2021 hearing, at 49:16-19 (“Ms. Heinz in correct that documents prepared a consultant could be privileged or work product. However, the important issue, as far as the Court’s concerned, is what is the primary purpose the documents were prepared”).

In this matter, the potential and preparation for litigation is self-evident. These documents were prepared in response to an FDA Warning Letter, the contents of which serve the basis for issues central to this litigation. It is objectively reasonable for an entity that receives an FDA Warning to believe that both litigation and future regulatory proceedings will ensue. *See, supra Miller v. J.B. Hunt Transp., Inc.*, 339 N.J. Super. 144, 150, 770 A.2d 1288 (App.Div.2001) (outlining an objectively reasonable standard for the work product protections). Furthermore, the objectively reasonable belief of litigation is highlighted by the fact that within a few months of the preparation of these documents, this lawsuit was filed. Of course, the contents of the Warning Letter and FDA-483 highlighted certain manufacturing processes

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that allegedly lead to the presence of nitrosamines, and the expectation that the FDA would discontinue its investigation after Aurobindo responded is unfounded. Rather, the expectation that the FDA would continue its investigation is more than reasonable, and the services of Meridan Consulting and ToxRox Consulting were obtained for this purpose. Furthermore, the proposition that litigation would ensue as a result of the Warning Letter and FDA-483 is reasonable as highlighted by the fact litigation did ensue a few months later. This sort of relationship was examined in *Todd v. STARR Surgical Co., supra*, wherein that Court extended the work product privilege to the Consultant's documents, and the work product privilege herein should be extended to the Meridan and ToxRox documents.

B. Attorney-Client Privilege

Generally speaking, “[c]ommunications between attorney and client are not privileged if made in the presence of or communicated to third parties.” *In re Niaspan Antitrust Litig.*, 2017 U.S. Dist. LEXIS 135753, *2, 2017 WL 3668907 (E.D.P.A. August 24, 2017), quoting *Barr Marine Products, Co. v. Borg-Warner Corp.*, 84 F.R.D. 631, 634 (E.D. Pa. 1979). Additionally, disclosing such information and communications to a third party waives the privilege. *In re Niaspan Antitrust Litig.* U.S. Dist. LEXIS 135753, *2. However, an exception to this rule exists, wherein, “disclosures made to a third-party consultant do not constitute a waiver when the disclosure is ‘necessary for the client to obtain informed legal

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advice’ or if the **disclosure is made ‘to an ‘agent’ assisting the attorney in giving legal advice to the client.’**” *Id.*, quoting *Westinghouse Elec. Corp. v. Republic of Phil.*, 951 F.2d 1414, 1423-24 (3d Cir. 1991); see also *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 352 F. Supp. 3d 207, 210 (E.D. NY Jan. 17, 2019 quoting *Upjohn Co. v. United States*, 449 U.S. 383, 389 (“[T]he privilege exists to protect not only the giving of professional advice to those who can act on it but **also the giving of information to the lawyer to enable him to give sound and informed advice.**”)

i. The Privilege Extends To Documents Belonging To Meridian and ToxRox Because Both Consultants Assisted Aurobindo’s Outside Counsel In Providing Legal Advice To Aurobindo

The Subpoenas should be quashed because all documents are protected by the attorney-client privilege since both consultants provided information to Aurobindo that was necessary for outside counsel to render legal advice to Aurobindo regarding its response to an FDA Warning Letter. Alternatively, Aurobindo requests entry of a protective order to allow counsel for Aurobindo to review the documents before they are produced to Plaintiffs’ counsel.

This case is factually similar to *In re Niaspan Antitrust Litig.*, 2017 U.S. Dist. LEXIS 135753. There, the Court ruled that information shared with outside counsel for the purpose of providing legal advice with respect to a promotion agreement was protected by the attorney-client privilege. *Id.* at *7. This sentiment was echoed in

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Federal Trade Commission v. GlaxoSmithkline, 352 U.S. App. D.C., 343, 294 F.3d 141, 147 (D.C. Cir. 2002), wherein the D.C. Circuit applied the attorney-client privilege to Glaxosmithkline's documents provided to outside consultants where the consultants were hired "to provide input to the legal department and/or receive the legal advice and strategies formulated by counsel." *Id.* The D.C. Circuit noted that the consultants hired by Glaxosmithkline were hired to render legal advice. *Id.* at 148.

Here, Aurobindo hired Meridian and ToxRox for the sole purpose of assisting its outside counsel in rendering legal advice to Aurobindo in response to an FDA warning letter. Such relationships and communications have routinely been protected by the attorney-client privilege. *See In re Niaspan Antitrust Litig.* U.S. Dist. LEXIS 135753, *2 (refusing to rule that disclosures to third parties hired to assist an attorney to give legal advice break the attorney-client privilege); *see also Federal Trade Commission v. GlaxoSmithkline*, 352 U.S. App. D.C., 343, 294 F.3d 141, 147 (D.C. Cir. 2002) (demonstrating a relationship between an attorney and consulting firm for the purpose of the attorney rendering legal advice is protected by the attorney-client privilege); *In re CV Therapeutics, Inc. Sec. Litig.*, 2006 U.S. Dist. LEXIS 41568, *20 (the privilege attaches to third party consults involved in rendering legal advice). Because Meridian and ToxRox were hired to assist

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Aurobindo in rendering legal advice, any documents in their possession are shielded by the attorney-client privilege.

For the foregoing reasons, the subpoenas must be quashed, or, alternatively, a Protective Order must be entered prohibiting plaintiffs from obtaining the documents possessed by Meridan Consulting and ToxRox Consulting, LLC.

I. Most of the Documents possessed by Meridan Consulting, and ToxRox Consulting, LLC are Draft Documents, and Should be Precluded From Disclosure to Plaintiffs' Counsel, and the Final Documents Have Already Been Produced

For the sake of argument, even if the documents possessed by Meridan Consulting and ToxRox Consulting, LLC, are not protected by the attorney-client privilege or work product doctrine, which Aurobindo contends they are, the vast majority of these documents are drafts. On January 5, 2021, Judge Schneider provided guidance on the issue of whether or not third party subpoenas should encompass draft documents. Specifically, Judge Schneider sustained an objection to Plaintiffs' request for draft documents as it related to third party subpoenas. *See* Transcript of Hearing held before Judge Schneider on January 5, 2021, at 63:17-19 (“So what I’m hearing, ZHP, is, one, the **Court sustains an objection to draft documents. We’re only talking about final documents.**” (emphasis added)). Toward the end of the conference, Judge Schneider indicated that,

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The Court: Here's what I think we should do, counsel: I think we've made tremendous progress during this phone call. **We've ruled on a number of issues.**

I do think the parties should go back, and, you know, sharpen their pencils, as the Court has said, and talk about these issues and the **Court's ruling with regard to the remaining subpoenas**....(emphasis added).

Id. at 70:15-23.

As ruled on by Judge Schneider, the third party subpoenas should not encompass draft documents. Plaintiffs' counsel, while negotiating the parameter of third party subpoenas pertaining to other entities, agreed that draft documents should be excluded. *See February 19, 2021, email with Plaintiffs' counsel*, attached hereto as Exhibit "A." Accordingly, Plaintiffs should not be permitted to receive any draft documents possessed by Meridan Consulting and ToxRox Consulting, LLC.

Respectfully submitted,

/s/ *Ethan R. Feldman*

Ethan R. Feldman

cc: Adam Slater, Esq. (via email, for distribution to Plaintiffs' Counsel)
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